

**PUBLISHED**

**UNITED STATES COURT OF APPEALS**

**FOR THE FOURTH CIRCUIT**

TAP PHARMACEUTICALS,

Plaintiff-Appellant,

v.

U.S. DEPARTMENT OF HEALTH &

No. 97-2773

HUMAN SERVICES; HEALTH CARE

FINANCING ADMINISTRATION;

PALMETTO GOVERNMENT BENEFITS

ADMINISTRATORS,

Defendants-Appellees.

Appeal from the United States District Court  
for the District of South Carolina, at Columbia.

Dennis W. Shedd, District Judge.

(CA-97-969-3-19)

Argued: September 22, 1998

Decided: November 30, 1998

Before MURNAGHAN, WILLIAMS, and MOTZ, Circuit Judges.

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Affirmed by published opinion. Judge Motz wrote the opinion, in which Judge Murnaghan joined. Judge Williams wrote an opinion concurring in part and concurring in the judgment.

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**COUNSEL**

**ARGUED:** Craig A. Hoover, HOGAN & HARTSON, L.L.P., Washington, D.C., for Appellant. Maria Simon, Appellate Staff, Civil Divi-

sion, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees. **ON BRIEF:** David G. Leitch, Adam Braff, HOGAN & HARTSON, L.L.P., Washington, D.C., for Appellant. Frank W. Hunger, Assistant Attorney General, J. Rene Josey, United States Attorney, Scott R. McIntosh, Appellate Staff, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees.

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## OPINION

DIANA GRIBBON MOTZ, Circuit Judge:

TAP Pharmaceuticals, Inc. (TAP), appeals from the dismissal of its complaint for lack of standing. TAP seeks to challenge a Medicare reimbursement policy. That policy reduces the amount of reimbursement paid for Lupron, a prostate cancer drug manufactured by TAP, to the amount paid for Zoladex, a competing prostate cancer drug made by another drug company. The district court concluded that the interests asserted by TAP in this action do not fall within the "zone of interests" protected by the Medicare Part B program, and that therefore TAP lacked standing to sue. Although we rely on reasons somewhat different than those set forth by the district court, we reach the same conclusion. Accordingly, we affirm.

### I.

Lupron and Zoladex treat prostate cancer by means of the same basic chemical mechanism, and they achieve the same level of effectiveness. The two drugs have different rates of action, however, and their particular chemical formulations implicate different adverse reactions.

Lupron is administered in liquid form by an intramuscular injection with a 22-gauge needle, while Zoladex is administered as a pellet injected under the skin with a larger, 14- or 16-gauge needle. The larger needle used in administering Zoladex may occasionally cause complications, such as keloid scarring or bleeding hematoma, which are less likely to occur with a Lupron injection. The manufacturer of

Zoladex suggests that, at the option of the physician or the patient, a local anesthetic and bandage be used in administering the drug. Such procedures are unnecessary with Lupron. Some doctors prefer Lupron to Zoladex because of its less invasive means of administration.

Many patients who receive Lupron or Zoladex have a portion of their health care costs covered by Medicare Part B, a federal program that provides supplementary medical insurance to the elderly. 42 U.S.C.A. §§ 1395j-1395ccc (West 1992 & Supp. 1998). Generally, Medicare Part B covers "reasonable and necessary" medical services for the "diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *Id.* §§ 1395k, 1395y(a)(1)(A). Though Medicare Part B does not cover most prescription medication, it does cover drugs, like Lupron and Zoladex, which are typically administered by doctors during office or hospital visits. *Id.* § 1395x(s)(2)(A). Medicare reimburses doctors for a percentage of the cost of such drugs. *Id.* §§ 1395k, 1395l, 1395u(o)(1); 42 C.F.R. § 405.517(b) (1998).

In October 1996, Palmetto Government Benefits Administrators (Palmetto), which administers Medicare Part B benefits in South Carolina under the authority of the Health Care Financing Administration and the United States Department of Health and Human Services (collectively, the Government), adopted the policy that TAP seeks to challenge here. The policy provides that doctors will be reimbursed for the cost of Lupron only at the reimbursement level of the less-expensive Zoladex. Prior to its adoption, Palmetto reimbursed expenditures for each drug on the basis of that drug's own cost.

Palmetto based this change in policy on its conclusion that "there is no therapeutic difference between" the two drugs, although it later acknowledged that TAP's Lupron has a greater duration of action. In the most recent version of the Lupron policy, Palmetto states that "there is no demonstrable difference in clinical efficacy" between Lupron and Zoladex. This latest version of the policy also loosens the restriction on Lupron reimbursement. It allows patients who wish to receive Lupron to make up the difference in cost between Lupron and Zoladex on their own, and it provides that "[i]f there are true medical indications requiring the use of [Lupron] instead of [Zoladex], Medicare will consider reimbursement for the difference in cost if an

invoice and documentation of the medical necessity accompanies the claim."

Palmetto maintains that the Medicare Carriers Manual authorized it to adopt the new Lupron policy. One provision of the Manual instructs carriers to pay for durable medical equipment (DME) at a level based on the least costly alternative where "medically appropriate and realistically feasible alternative pattern[s] of care" are available. Compl. at 5 (quoting Manual § 2100.2(B)). Another provision of the Manual states that carriers have "discretion" to apply the least costly alternative principle "to payment for non-DME items and services as well." See id. (quoting Manual § 7505.1).

TAP alleges that the new Lupron reimbursement policy violates a Medicare regulation providing that reimbursement for drugs such as Lupron must be "based on the lower of the estimated acquisition cost or the national wholesale average price of the drug." 42 C.F.R. § 405.517(b). TAP asserts that basing reimbursement for Lupron on the cost of Zoladex, rather than on the cost of Lupron itself, violates this regulation. Although the regulation has now been superseded by a 1997 amendment to the Act, which provides that payment for covered drugs is to be made at 95% of the average wholesale price, 42 U.S.C. § 1395(o)(1), TAP's contention regarding the regulation applies equally well to the statute as amended. <sup>1</sup> Both base reimbursement on the cost of the drug used, while the new Lupron policy bases reimbursement on the cost of another drug.

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<sup>1</sup> Prior to the 1997 amendments, the statutory provisions governing reimbursement for medication also indicated, albeit less clearly than the regulation relied on by TAP, that reimbursement was to be based on the cost of the drug actually provided. Section 1395l(a), the section that determines the amount of benefits in most cases, provides for payment of a percentage of the cost of "the services," which clearly means the services actually provided to the beneficiary. 42 U.S.C.A. § 1395l(a) (West 1992). Drugs like Lupron and Zoladex come within the definition of "medical and other health services," id. § 1395x(s)(2), and therefore the benefit amount provisions of section 1395l would apparently have applied to them prior to the 1997 amendments. Since those amendments came into effect, however, the more specific language of section 1395u(o)(1) has controlled reimbursement for drugs, as noted in the text.

TAP also alleges that Palmetto adopted its Lupron policy without the notice and comment required by statute, see 5 U.S.C.A. § 553 (West 1996); 42 U.S.C.A. § 1395hh(a)(2),(b) (West 1996); that Palmetto's conclusion that "there is no therapeutic difference between" Lupron and Zoladex lacked a scientific basis and so its adoption of the new Lupron policy in reliance upon this conclusion was arbitrary and capricious, see 5 U.S.C.A. § 706(2); and finally that Palmetto's reimbursement policy violated 42 U.S.C.A. § 1395y(a)(1)(A), which prohibits payment for any item that is not "reasonable and necessary."

Without confronting the merits of these allegations, the Government moved to dismiss TAP's complaint on three grounds. The Government argued (1) that TAP's complaint did not meet prudential standing requirements; (2) that Medicare Part B statutorily precluded TAP's complaint; and (3) that TAP lacked Article III standing. The district court dismissed TAP's complaint based solely on the first of these contentions, finding that the company did not satisfy the prudential standing requirements and therefore had no right to challenge the Lupron policy in court. In light of our resolution of this appeal, we too need only address the first issue.

## II.

The Administrative Procedure Act (APA) provides that "[a] person suffering legal wrong, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C.A. § 702 (West 1996). The Supreme Court, however, has concluded that the APA in fact provides more limited rights than the statutory language might suggest. In accordance with its prudential standing rules, the Court has held that the APA permits a party to challenge agency action in court only if "the interest sought to be protected by the complainant is arguably within the zone of interests to be protected or regulated by the statute . . . in question." Association of Data Processing Serv. Orgs. v. Camp, 397 U.S. 150, 153 (1970) (interpreting 5 U.S.C. § 702).

For a number of years the Supreme Court did not further explain how this "zone of interests" test was to be applied. In the interim, we and other courts concluded that "the zone test rests on the need to secure the benefits of a statutory program for the groups that Con-

gress intended to benefit," Leaf Tobacco Exporters Ass'n v. Block, 749 F.2d 1106, 1111 (4th Cir. 1984) (emphasis added); see also Moses v. Banco Mortgage Co., 778 F.2d 267, 270 (5th Cir. 1985) ("[a] party will fall within the zone of interests if he is a member of a class of persons who was intended to be benefited by the statute or regulation"); Alschuler v. Department of Housing and Urban Development, 686 F.2d 472, 480 (7th Cir. 1982) (denying standing to nonresidents where relevant statutory provision was "designed solely for the protection of residents"); Constructores Civiles de Centroamerica v. Hannah, 459 F.2d 1183, 1189 (D.C. Cir. 1972) ("the challenging party need only show that it is an intended beneficiary of the statute not necessarily the primary one").

Thus, we held in Leaf Tobacco that a tobacco exporters association did not assert an interest within the zone that Congress intended to protect in the Commodity Credit Corporation Charter Act, 15 U.S.C.A. §§ 714, 714c (West 1997), and that it therefore lacked standing to challenge the statute. Leaf Tobacco, 749 F.2d at 1114-15. Although we recognized that a provision of the statute arguably protected the association's asserted interests, we nonetheless denied the association standing because the statute "explicitly serve[d] the interests of identifiable groups," and the association was not among those groups. Id. at 1115. We explained that "[w]here Congress has . . . clearly defined the class to be protected, the zone test works to prevent groups outside of the class from usurping the legislative entitlement." Id. For similar reasons, a few years later, we held that commercial banks lacked prudential standing to challenge a provision in the Federal Credit Union Act because that statute's common bond provision "was designed" to further the interests of credit unions, and "[t]here [wa]s no evidence . . . that Congress also intended by this provision to protect the competitive interests of banks." Branch Bank and Trust Co. v. National Credit Union Admin. Bd., 786 F.2d 621, 626 (4th Cir. 1986).

The district court relied on Leaf Tobacco and Branch Bank to hold that TAP lacked prudential standing here. TAP points out that after we issued those rulings, the Supreme Court clarified the zone of interests test by stating that courts, in applying the test, should "not inquire whether there has been a congressional intent to benefit the would-be plaintiff." National Credit Union Admin.[NCUA] v. First Nat'l Bank

& Trust Co., 118 S. Ct. 927, 933 (1998); see also Clarke v. Securities Indus. Ass'n, 479 U.S. 388, 399-400 (1987) (the zone of interests test "is not meant to be especially demanding; in particular, there need be no indication of congressional purpose to benefit the would-be plaintiff"). Indeed, the Supreme Court applied its broader conception of the zone of interests test in NCUA to hold that the competitive interests of banks come within the zone of interests protected by the common bond provision of the Federal Credit Union Act, overruling our holding in Branch Bank, NCUA, 118 S. Ct. at 932 n.1 (noting that Branch Bank conflicted with the lower court's opinion in NCUA, which the Court went on to affirm).

In view of these intervening developments in the law, TAP maintains that the district court erred in holding that TAP did not assert interests within the zone protected by Medicare Part B.

The Supreme Court in NCUA and Clarke did significantly broaden what we had understood to be the proper reach of the zone of interests test. But the Court did "not eviscerat[e] the test." NCUA, 118 S. Ct. at 936 n.7 (internal quotation marks omitted). Rather, it expressly reaffirmed its validity, explaining that when, as here, "the plaintiff is not itself the subject of the contested regulatory action, the test denies a right of review if the plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." Clarke, 479 U.S. at 399; see also NCUA, 118 S. Ct. at 934 (citing Clarke). Hence, standing will be denied to parties who are "merely incidental beneficiaries" of a statute. NCUA, 118 S. Ct. at 936 n.7. The NCUA Court described the zone of interests test as a two-part inquiry:

in applying the "zone of interests" test, we do not ask whether, in enacting the statutory provision at issue, Congress specifically intended to benefit the plaintiff. Instead, we first discern the interests "arguably . . . to be protected" by the statutory provision at issue; we then inquire whether the plaintiff's interests affected by the agency action in question are among them.

Id. at 935. In the instant case, therefore, we must initially determine what interests the Medicare Part B program "arguably" protects. We

must then ask whether the interests of TAP that allegedly have been affected by the challenged agency action--i.e., the Lupron policy--are among the interests arguably protected by Medicare Part B.

### III.

#### A.

The Government maintains that the only interest arguably protected by the Medicare Part B program is the interest "of the elderly in receiving affordable medical insurance," and that TAP's commercial interests are at odds with this statutory goal. Brief of Appellees at 20. In support of this position, the Government cites the statute's provision of insurance for the cost of "reasonable and necessary" medical care. 42 U.S.C.A. § 1395y(a)(1)(A). The Government argues that this statutory language shows Congress's sole intention in enacting this legislation to have been that of protecting the financial integrity of the Medicare program.

TAP contends that the most important interest protected by the Medicare Part B program is the provision of excellent medical care to the elderly. It accordingly denies that the "reasonable and necessary" language in the statute involves a cost limitation, as the Government has argued; instead, TAP maintains that the phrase has long been interpreted by the Government itself to mean merely "safe and effective." Brief of Appellant at 5; see Estate of Aitken v. Shalala, 986 F. Supp. 57, 59 (D. Mass. 1997). TAP also argues that the Government's failed attempts to promulgate a regulation introducing a cost-based limitation show that the existing regulatory scheme has no such limitation. Brief of Appellant at 6-7 (citing 54 Fed. Reg. 4302 (Jan. 30, 1989)). TAP heavily relies on a phrase in the legislative history stating that Medicare Part B seeks "to make the best of modern medicine more readily available to the aged." S. Rep. No. 89-404 (1965), reprinted in 1965 U.S.C.A.N.N. 1965. TAP contends that its commercial interests in selling as much Lupron as possible coincide with this statutory goal.

Both parties provide a distorted picture of the interests "arguably protected" by Medicare Part B. Their conflicting positions suggest what our examination of the statute, the regulations, and the legisla-



tive history leads us to conclude: Medicare Part B, like many statutes, embodies a compromise between ideals of achievement and economic feasibility that puts its basic purposes in tension. The Act seeks to "make the best of modern medicine more readily available to the aged," but it tries to do so by covering only "reasonable and necessary" care in a manner that will ensure the financial integrity of the system. Perhaps the clearest indication of the statute's competing goals appears in its provision establishing that health care services will generally be covered at a statutorily-defined percentage of their cost. 42 U.S.C.A. § 1395j (West 1992 & Supp. 1998). Through this provision, the Act makes all levels of reasonable and necessary medical care more readily available to the aged, while at the same time discouraging excessive expenditure by requiring beneficiaries to pay for a proportionate share of the cost of the services they use.

To have standing, however, TAP need not assert an interest that coincides precisely with the balance struck by Congress between the Act's conflicting purposes; rather, it need only show that its "interests affected by the agency action" are "among" those that Congress arguably sought to protect. NCUA, 118 S. Ct. at 935.

Considering only the statute's interest in providing high-quality medical care does not lead to a resolution favorable to TAP, however. Contrary to TAP's assertions, the interest that it asserts here is not the same as the statute's interest in making the best of medicine more readily available to the aged. TAP seeks to increase distribution of Lupron, but it does not specifically allege that Lupron is the best of medicine, and it has not otherwise definitively contended that LUPRON is "better" than Zoladex.

Even if we regard TAP's more general allegations as asserting the superiority of Lupron, the statute's interest in "mak[ing] the best of modern medicine more readily available to the aged" would not coincide with TAP's interest. Quotation of the entire sentence in which this much-cited fragment of legislative history occurs makes the difference plain: "The provision of insurance against the covered costs would encourage the participating institutions, agencies, and individuals to make the best of modern medicine more readily available to the aged." S. Rep. No. 89-404 (1965), reprinted in 1965 U.S.C.A.N.N. 1965. This statement expresses an expectation that, as a result of the

coverage of health care costs under Medicare Part B, hospitals, health care agencies, and doctors will become less reluctant to provide high-quality medical care to elderly patients. Medicare Part B is here envisioned as a means of rectifying a situation in which health care providers denied first-rate services to the aged because they lacked insurance. The main import of the statement, then, is that the statute seeks to make the best of medicine "more readily available" than it would be in the absence of Medicare Part B. The Lupron policy achieves this statutory purpose: Lupron is still covered, reimbursement for a portion of its cost is still provided, and Lupron is thus made more readily available to the aged than it would be in the absence of Medicare Part B. TAP's interest in attacking the Lupron policy must therefore be in something other than making the best of medicine more available in the sense articulated in the legislative history.

TAP actually seeks not to make Lupron "more readily available" than it would be without Medicare Part B, but rather to make it more available than it is now, under the Lupron policy. In this sense, TAP's asserted claim strives for something very different than that which the legislative history identifies as a statutory goal. Moreover, TAP objects to the present reimbursement policy not because it fails to make Lupron more available, but because it fails to make Lupron available on the same basis as Zoladex. The legislative history stating that the statute seeks "to make the best of modern medicine more readily available to the aged," however, cannot be read to express an interest in making different treatments for the same condition available on the same basis. The interest of TAP that is "affected by the agency action in question," therefore, does not coincide with the statute's interest in making the best of medicine more available to Medicare recipients.<sup>2</sup>

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<sup>2</sup> We recognize that in so holding we are rejecting the position taken in Ioptex Research v. Sullivan, 1990 WL 284512 (C.D. Cal. Dec. 10, 1990), upon which TAP heavily relies. In this unpublished opinion the court held that a manufacturer of intraocular lenses had standing to challenge a Medicare reimbursement policy that reduced the availability of its product. Id. at \*2. The court based this ruling on its conclusion that "Ioptex's interest in gaining wider distribution of its[lenses] is not inconsistent with or only marginally related to the Medicare Act's purpose of

B.

Although TAP addresses the point only in passing, its basic claim raises another interest that could be among those "arguably protected" by Medicare Part B. This is TAP's interest in enforcing the regulatory and statutory provisions that require reimbursement for a drug to be based not on the cost of a competing drug, as in the Lupron policy, but rather on the cost of the drug itself. See 42 U.S.C. § 1395u(o)(1); 42 U.S.C. § 1395j; 42 C.F.R. § 405.517(b).

The Supreme Court's decision in NCUA could be read to suggest that the bare assertion of such an interest would be enough to overcome prudential limitations on standing. There the Court held that banks challenging an agency policy that allegedly violated the "common bond" provision of the Federal Credit Union Act satisfied the zone of interests test. NCUA, 118 S. Ct. at 936-38. The Court reached this conclusion even though nothing other than the common bond provision itself indicated a congressional concern for banks, their competitive interests, or competition in general. Id. TAP has alleged that the Lupron policy violated the Medicare Act to its detriment, and so its claim would survive under this interpretation of the zone of interests test.

This broad interpretation of the rule in NCUA was advanced, however, by the dissent in that case; the majority expressly rejected it, stating that its own formulation of the zone of interests test could not "be read to imply that in order to have standing under the APA, a plaintiff must merely have an interest in enforcing the statute in question." 118 S. Ct. at 936 n.7. As an indication of the difference between this rejected version of the test and the holding of NCUA, the Court noted that the plaintiff banks were "more than merely incidental

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making the best of medicine available to the elderly." Id. We believe, for the reasons set forth in text, that this constitutes a misunderstanding of the legislative history of Medicare Part B. That history does not articulate a congressional purpose to make "the best of medicine readily available to the elderly"; rather, it states an expectation that the statute will make the best of medicine more readily available than it would be if Medicare Part B did not exist.

beneficiaries of [the common bond provision's] effects on competition." Id. This "incidental beneficiary" concept reiterates the principle, articulated in Clarke, that the zone of interests test "denies a right of review if the plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed the Congress intended to permit the suit." Clarke, 479 U.S. at 399. Neither NCUA nor Clarke suggests, however, that when a party is more than merely an incidental beneficiary of the statute, it necessarily satisfies the zone of interest test. Still the concept is important because both cases do indicate that a party who is merely an incidental beneficiary cannot meet the test. Thus if TAP is merely an incidental beneficiary of the statute, it fails to satisfy the relevant prudential standing requirements no matter how acutely it desires to enforce the statute's provisions.

Drug companies like TAP certainly do not constitute direct beneficiaries of the Medicare Part B program. But NCUA indicates that they do qualify as something more than merely incidental beneficiaries. A statute that strives to make medical care more available to the elderly directly implicates the interests of drug companies by expanding their markets, just as (albeit conversely) the statute promoting the growth of credit unions in NCUA directly implicated the interests of competing financial institutions by working, in effect, to contract their markets.

The Supreme Court's decision in Lujan v. National Wildlife Fed'n, 497 U.S. 871 (1990), provides another indication that TAP is more than merely an incidental beneficiary. The Court there used a hypothetical to define the limits of standing under the APA:

for example, the failure of an agency to comply with a statutory provision requiring "on the record" hearings would assuredly have an adverse effect upon the company that has the contract to record and transcribe the agency's proceedings; but since the provision was obviously enacted to protect the interests of the parties to the proceedings and not those of the reporters, that company would not be "adversely affected within the meaning" of the statute.

Id. at 883 (quoting 5 U.S.C. § 702). TAP persuasively asserts that "[i]n contrast to the purely procedural and incidental involvement of

[the] transcribers' interest in the Lujan example, the manufacturers of cancer drugs are a substantive and essential part of the system that" makes the best of medicine more available to the aged. Brief of Appellant at 16. In terms similar to those in the Lujan example, TAP's claim would be roughly equivalent to that of a case reporting company seeking to enforce a provision of a statute that was enacted for the principal purpose of encouraging courts to publish their decisions, and that operated by reimbursing courts for the costs of publication. In the same way that one of the principal purposes of Medicare Part B--to make medical care more available to the aged--directly implicates the interests of drug companies like TAP, the main purpose of the case publication statute directly implicates the interests of case reporting companies. The statutory provision in the Lujan example, by contrast, was presumably enacted as part of a statutory scheme that had a principal purpose other than that of holding hearings on the record, and so the reporting company's interest there could fairly be described as incidental or "marginally related" to that purpose. Compared to the plaintiff in the Lujan example, then, TAP does not appear to be merely an incidental beneficiary.

As noted above, however, a determination that TAP is not merely an incidental beneficiary does not mean that it necessarily passes the zone of interests test. It only means that TAP's claim cannot be rejected on this basis. Other than the "incidental beneficiary" standard, which has proved inconclusive here, NCUA set forth no specific guidelines for evaluating cases, like this one, where a party's claim to standing rests solely on an asserted interest in the enforcement of a statutory provision. But, the entire thrust of the NCUA holding reiterates the validity of a zone of interests test that requires something more than Article III standing. Accepting an interpretation of the test broad enough to accommodate TAP's claim to standing here would make discernment of this additional element almost impossible.

In these circumstances, we do best to hew closely to the particulars of Supreme Court precedent in determining the limits of the zone of interests test. The NCUA holding resulted only in a finding that commercial competitors of the entities directly regulated by the statute satisfy the zone of interests test. Although the NCUA Court did not expressly limit its rationale to competitors, it did rely almost entirely on cases in which competitors were found to have standing. See

Clarke, 479 U.S. at 403; Investment Co. Inst. v. Camp, 401 U.S. 617, 621 (1971); Arnold Tours, Inc. v. Camp, 400 U.S. 45, 46 (1970) (per curiam); Data Processing, 397 U.S. at 157.

Furthermore, the NCUA Court's discussion of Air Courier Conference v. American Postal Workers Union, 498 U.S. 517 (1991) -- the only case not dealing with competitors that it explicitly addressed -- also turned in part on the issue of competition. NCUA, 118 S. Ct. at 938 (citing Air Courier, 498 U.S. at 528 n.5). In Air Courier, postal workers challenged a Postal Service regulation suspending the Service's monopoly over some international operations. 498 U.S. at 519-21. The postal workers claimed that the regulation violated the APA and the postal monopoly statutes in a manner that adversely affected their interests in maximizing employment opportunities. Id. at 521. The Court ruled that the workers did not come within the zone of interests that the monopoly statutes sought to protect. Id. at 519, 530. The Court in NCUA distinguished its own ruling from that in Air Courier by referring to the Air Courier Court's mention of competitive interests: "We further noted [in Air Courier] that although the statute in question regulated competition, the interests of the plaintiff employees had nothing to do with competition." NCUA, 118 S. Ct. at 938 (citing Air Courier, 498 U.S. at 528 n.5).

The Court's discussion of its prior zone of interests cases in NCUA thus suggests that a party who is not expressly subject to a statute's provisions can only pass the zone of interests test if it asserts the interests of a competitor of the subject class. Data Processing supports this approach. The Court there granted the competitor plaintiffs standing based in part on the rationale that "those whose interests are directly affected by a broad or narrow interpretation of the Acts are easily identifiable." 397 U.S. at 157. When, as here, a statute concerns a specified class, those whose interests are most directly affected by a broad or narrow interpretation of the statute are even more easily identifiable. As Data Processing and its progeny suggest, they are the parties expressly subject to the statute and the commercial competitors of such parties.

The Supreme Court rulings providing commercial competitors with standing reflect the principle that when Congress passes a statute regulating a defined class, its intention to limit the class must be given

the same respect as its intention to regulate it. Defined limits on the scope of a statute express a congressional purpose to regulate so far, and no farther. Where, as in the instant case, commercial interests are concerned, this legislative restraint can be presumed to indicate a Congressional intention to protect the interests of the competitors of the parties regulated from encroachment beyond that caused by the statute's terms. Such a presumption can safely be made because, in the commercial sphere, benefit or detriment to one party can be fairly assumed to have the opposite effect on the interests of the party's competitors. We therefore hold that where a statute defines a group that is subject to its provisions, a party asserting commercial interests satisfies the zone of interests test only if its interests put it in the same position as a member of the subject group or a commercial competitor of such a member.<sup>3</sup>

We do not believe that this approach falls afoul of NCUA's rule that a court should "not ask whether, in enacting the statutory provision at issue, Congress specifically intended to benefit the plaintiff." 118 S. Ct. at 935. The context of that statement shows that the Supreme Court sought only to prohibit an automatic denial of standing in cases where no positive evidence of a congressional intent to benefit the plaintiff can be found. An approach that provides standing to parties based on their assertion of commercially competitive interests presents no conflict with this principle. Furthermore, our approach relies not on the identity of the party but on the nature of the interest that it asserts, as the terms of the zone of interests test have always required. Data Processing, 397 U.S. at 153.

When we apply this analysis to the case at hand, it becomes clear that TAP does not satisfy the zone of interests test. TAP seeks to lower the cost of Lupron to beneficiaries of Medicare Part B, and

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<sup>3</sup> We recognize that those asserting noncommercial interests present a different question. The Court in Data Processing made it clear that aesthetic, conservational, recreational, and other noneconomic values can come within a statute's zone of interests. Data Processing, 397 U.S. at 153-54. Such interests do not readily lend themselves to characterization as competitive or noncompetitive. Thus the analysis set forth in the text would likely be of little use in determining if those asserting noncommercial interests fall within a statute's zone of interests.

thereby to regain the market share that it allegedly lost because of the Government's Lupron policy. The interest that TAP asserts here is thus clearly a commercial interest, but it is not an interest that puts it in the position of either a party expressly subject to the Act or a competitor of such a party.

The parties expressly subject to the Act are beneficiaries and their assigns, *see* 42 C.F.R. § 424.55, whose statutorily-protected interests are in the direct receipt and provision of "reasonable and necessary" medical services, 42 U.S.C.A. 1395y(a)(1)(A). TAP obviously does not receive medical services. The company is manifestly interested in the provision of Lupron to patients, but it does not directly provide the drug to patients. Thus, TAP's interests differ from those who receive or directly provide medical services pursuant to Medicare Part B.

Furthermore, as the Government notes, TAP does not assert an interest in providing "reasonable and necessary" medical services; rather it asserts an interest in increasing sales of Lupron. The commercial character of TAP's interest in the sale of Lupron does not, of course, impair its claim to standing. *NCUA*, 118 S. Ct. at 938. The difference between TAP's commercial interest and the interests of the parties expressly subject to the Act, however, does.

Finally, TAP's asserted interest here also fails to identify it as a commercial competitor of a party who is subject to the statute. TAP competes with the manufacturer of Zoladex, not with Medicare Part B beneficiaries. Moreover, although the medical professionals who prescribe and provide medication under Medicare Part B do affect TAP's revenues, they do not compete with TAP in the wholesale drug market.

We, therefore, hold that TAP does not come within the zone of interests that Medicare Part B was designed to protect. The order of the district court granting the Government's motion to dismiss TAP's complaint is accordingly

AFFIRMED



WILLIAMS, Circuit Judge, concurring in part and concurring in the judgment:

I concur in Parts I, II, III.A and in the judgment. With respect, however, I cannot concur in Part III.B.

The discussion contained in Part III.B is premised on TAP's argument that it was within the zone of interests of Medicare Part B merely because it had an interest in enforcing the provisions of the statutory and regulatory scheme. In my view, that argument was not fully briefed and argued before the court and therefore was not properly raised. See Canady v. Crestar Mortgage Corp., 109 F.3d 969, 973 (4th Cir. 1997). As a result, I conclude that the discussion contained in Part III.B is unnecessary.